

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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STEPHANIE DIMASI, * No. 15-1455V
* Special Master Christian J. Moran
Petitioner, *
* Filed: November 7, 2019

v. *

SECRETARY OF HEALTH * Entitlement, motion for ruling on the
AND HUMAN SERVICES, * record, influenza (“flu”) vaccination,
* small fiber neuropathy, postural
Respondent. * orthostatic tachycardia syndrome
* (“POTS”)

* * * * *

Howard S. Gold, Gold Law Firm, LLC, Wellesley Hills, MA, for petitioner;
Claudia B. Gangi, United States Dep’t of Justice, Washington, DC, for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION¹

Stephanie DiMasi alleged that an influenza vaccination was the “causation-in-fact” of her small fiber neuropathy and postural orthostatic tachycardia syndrome (“POTS”). Pet’r’s Am. Mot., July 7, 2019, at 1. Ms. DiMasi has specifically denied that her conditions pre-dated the influenza vaccination and, relatedly, does not allege a significant aggravation claim. *Id.* at 21. Following the submission of expert reports, the parties agreed that the record was complete. Ms. DiMasi declined to offer any oral testimony at a hearing and moved for a ruling on the record.

¹ The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website (<https://www.uscfc.uscourts.gov/aggregator/sources/7>). Thus, anyone can access the decision via the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

The evidence supports a finding that Ms. DiMasi's conditions pre-dated the influenza vaccination. Thus, Ms. DiMasi has not established that she is entitled to compensation.

I. Factual Overview²

Because whether Ms. DiMasi's symptoms existed before the vaccination is critical, her pre-vaccination medical history is presented more extensively.

A. Before the December 4, 2012 vaccination

At a hospital admission on March 19, 2008, Ms. DiMasi reported near syncope and premature ventricular contractions. Exhibit 6 at 52, exhibit 11 at 11. The record noted that Ms. DiMasi had an event monitor to track the status of her heart. Id. A subsequent MRI of Ms. DiMasi's internal auditory canals and brain along with an ultrasound of Ms. DiMasi's lower extremities were found to be normal. Exhibit 11 at 13 (March 2008 ultrasound), 14 (April 2008 MRI).

In May and June 2009, Ms. DiMasi engaged in physical therapy to address cervical/thoracic spine issues. Exhibit 15 at 1-3. At an August 11, 2009 appointment with Dr. Fischer, a neurologist, Ms. DiMasi reported headaches that interrupted her sleep. Id. at 3. The record for Ms. DiMasi's appointment listed many problems, including peripheral neuropathy, palpitations, premature ventricular contractions, and migraine headaches. Id.

On November 2, 2009, Ms. DiMasi was again admitted to the hospital for near syncope and a history of palpitations was noted. Exhibit 16 at 12-13, 27, 34. On December 7, 2009, Ms. DiMasi saw Dr. Rho complaining of intermittent episodes of mild dizziness for the last month. Exhibit 15 at 6. Dr. Rho attributed her symptoms to migraine-associated vertigo. Id.

In later medical records, Ms. DiMasi asserts that she received the 2011 influenza vaccination and reported that she had mild tachycardia, lightheadedness, and dizziness for 30 minutes. Exhibit 17 at 28 (July 14, 2015 appointment with Dr. Cros). Ms. DiMasi has not submitted any medical records to document her

² The undersigned has reviewed all the records. However, this decision does not recite all of them.

2011 influenza vaccination or instances where she reported the alleged symptoms at any point soon after the 2011 vaccination.

At an April 18, 2012 follow-up appointment with Dr. Fischer, Ms. DiMasi complained of “intermittent tingling behind her knees and upper calves, particularly when she sits for prolonged periods of time.” Exhibit 15 at 17. In the record for the visit, a “neurology problem list” identifies migraine headache, fibromyalgia, and intermittent vertigo. *Id.* At an August 14, 2012 visit with Dr. Fisher, Ms. DiMasi described an incident in May with a “headache loss of memory,” possibly a syncopal event, that may have been caused by alcohol consumption. *Id.* at 21. Ms. DiMasi said she was assessed at a local hospital after this incident, but Dr. Fischer noted that he did not have the records for that visit. *Id.*³

On December 4, 2012, Ms. DiMasi received an influenza vaccination. Exhibit 3. She then saw several doctors in December 2012.

B. After the December 4, 2012 vaccination

On December 5, 2012, Ms. DiMasi saw her primary care provider, Dr. Sen, and reported some tachycardia and a “weird” sense of throat tightening. Exhibit 6 at 46. Dr. Sen noted that Ms. DiMasi had a history of premature ventricular contractions, determined that the EKG did not have the same results, and transferred Ms. DiMasi to the hospital via ambulance for further testing. After spending the night at the emergency room, Ms. DiMasi was discharged with a diagnosis of tachycardia. Exhibit 13 at 12. On December 8, 2012, Ms. DiMasi returned to the hospital complaining of neurological symptoms in her left leg. Exhibit 6 at 48. She was discharged with a diagnosis of elevated blood pressure. Exhibit 13 at 15.

Ms. DiMasi went back to see Dr. Sen on December 10, 2012, complaining of dizziness, left leg neurological symptoms, weakness, and palpitations. Exhibit 6 at 48. On December 12, 2012, Ms. DiMasi visited Dr. Stone, a cardiologist, who noted that she had fewer palpitations since stopping caffeine. Exhibit 5 at 4.

³ It does not appear that the medical records for this hospital visit are in the record.

Ms. DiMasi saw Dr. Chen at a neurology outpatient clinic on December 19, 2012, and reported that “immediately after the flu shot she had a sensation of dizziness, tachycardia, shakiness, generalized weakness and tingling behind the right knee.” Exhibit 13 at 17. After the vaccination, Ms. DiMasi said she “was monitored for 1 - 1/2 hours and her blood pressure was noted be elevated along with tachycardia. The symptoms subsided a little bit and she was discharged home.” Id. In his impressions, Dr. Chen found it “hard to explain what could cause such a rapid response.” Id. at 18.

On December 27, 2012, at a follow-up with Dr. Fischer, Ms. DiMasi described an “immediate response” after the vaccination, “within a few minutes,” of a rapid heart rate, dizziness, tingling and numbness rising from left leg up her back. Exhibit 7 at 1. In his assessment, Dr. Fischer noted that “given the unilateral nature of the symptoms, it is somewhat difficult to understand how the injection could result in these symptoms.” Id. at 4. This December 27, 2012 appointment with Dr. Fischer was the last appointment in December 2012.

Ms. DiMasi’s symptoms continued in waxing and waning course without much clarity on a diagnosis throughout 2013.⁴ On May 19, 2014, Dr. Gorson, a neurologist, suggested that a diagnosis of POTS could possibly explain Ms. DiMasi’s recurrent tachycardia and dizziness. Exhibit 10 at 2.

On May 20, 2015, Dr. Kaplan, a neurology resident, offered an alternative opinion that Ms. DiMasi’s symptoms were the result of an HSV-2 recurrence. Exhibit 8 at 1-3. Another alternative explanation was offered on June 2, 2015, by Dr. Shoap, a cardiologist, who knew Ms. DiMasi personally from working together. Dr. Shoap was “convinced that this is all anxiety, hyperventilation – psychoneurotic and is not ‘organic.’” Exhibit 14 at 108.

On August 8, 2016, Dr. Bhattacharyya, a neurologist, stated Ms. DiMasi’s course of symptoms “would best fit with post-flu small fiber neuropathy,” but noted that they were still “work[ing] to figure out her syndrome.” Exhibit 21 at 4.

⁴ These records have been reviewed but are not addressed individually here.

On October 20, 2016, Dr. Novak, a neurologist, conducted autonomic testing and a skin biopsy. Based upon the results of that testing, Dr. Novak diagnosed Ms. DiMasi with (1) small fiber neuropathy, (2) POTS (most likely due to the small fiber neuropathy), (3) baroreflex failure, and (4) mild autonomic failure (due to small fiber neuropathy). Exhibit 23 at 9. While Ms. DiMasi has continued to seek treatment, the medical records described thus far are the most relevant for adjudicating Ms. DiMasi's vaccine claim.

II. Procedural History

Ms. DiMasi alleged that the December 4, 2012 influenza vaccination caused her to develop peripheral neuropathy. Pet., filed Dec. 2, 2015, at 1. Ms. DiMasi submitted her medical records and a statement of completion on February 19, 2016. After outstanding medical records were identified by the Secretary, Ms. DiMasi submitted additional records.

On September 19, 2016, the Secretary filed his Rule 4 report recommending against compensation. In the report, the Secretary noted that Ms. DiMasi had a complex medical history preceding the vaccination, that she complained of tingling more than six months before the vaccination, and she reported tingling minutes after the vaccination. Resp't's Rep. at 2, 7-8.

After a few extensions of time, Ms. DiMasi filed an expert report from Dr. Marcel Kinsbourne on March 27, 2017. Dr. Kinsbourne did not address Ms. DiMasi's pre-vaccination medical history that was discussed in the Rule 4 report and noted Dr. Novak's diagnosis of small fiber neuropathy⁵ and POTS. Exhibit 24 at 2, 4. Dr. Kinsbourne concluded that the influenza vaccine caused Ms. DiMasi to develop small fiber neuropathy within a day. *Id.* at 8.

Following some additional extensions of time, the Secretary filed an expert report from Dr. Thomas Leist on October 26, 2017. Dr. Leist detailed Ms. DiMasi's pre-vaccination history back to 2008 noting recurring episodes of syncope/near syncope, palpitations, and tachycardia. Exhibit A at 1-2, 9. Dr. Leist concluded that Ms. DiMasi had small fiber neuropathy prior to the influenza vaccination. *Id.* at 9. Dr. Leist then filed a supplemental expert report to address diagnosis and medical theory. Exhibit E, filed Jan. 5, 2018. Dr. Leist expanded

⁵ Dr. Kinsbourne describes Ms. DiMasi's condition as acute autonomic and sensory neuropathy ("AASN"), a subset of small fiber neuropathy, but, given the grounds for this decision, Ms. DiMasi's condition will be referred to as "small fiber neuropathy" for the sake of simplicity.

this opinion to deny that the influenza vaccination significantly aggravated Ms. DiMasi's pre-existing small fiber neuropathy. Id. at 1-2.

On May 18, 2018, Ms. DiMasi filed a supplemental expert report from Dr. Kinsbourne. In the report, Dr. Kinsbourne acknowledged Dr. Leist's description of pre-vaccination episodes of syncope/near syncope, palpitations, and tachycardia. Dr. Kinsbourne explained these problems are not surprising as it is "not unusual for the onset of POTS to be preceded by miscellaneous episodes of dysautonomia." Exhibit 25 at 2.

At a status conference on May 30, 2018, the parties decided to explore settlement before proceeding with further litigation. After submitting progress reports on settlement, a status conference was held on October 3, 2018, to discuss next steps. The Secretary stated his intent to defend the case, and Ms. DiMasi requested adjudication of the case based on the existing record, without any oral testimony taken at a hearing. Thus, the undersigned issued an order for submissions describing in detail the preferred components of the parties' filings. Order, issued Oct. 4, 2018.

After Ms. DiMasi had submitted a motion for ruling on the record, the Secretary had submitted a response, and Ms. DiMasi concluded with a reply, a status conference was held on May 29, 2019. The undersigned noted several aspects of the filings that did not comply with the October 4, 2018 order for submissions. A new briefing schedule was set to allow the parties to remedy their submissions. Order, issued May 29, 2019.

On July 7, 2019, Ms. DiMasi filed an amended motion for ruling on the record. The Secretary filed an amended response on August 9, 2019. Ms. DiMasi did not file a reply. This matter is now ripe for adjudication.

III. Standards for Adjudication

The authority giving special masters the discretion to either hold an evidentiary hearing or to decide the case on the written record is 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in D'Tiole v. Sec'y of Health & Human Servs., 726 F. App'x 809, 812 (Fed. Cir. 2018) (holding that a special master did not abuse his discretion by deciding a case without holding an evidentiary hearing).

Petitioners are required to prove their cases by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not.

Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

IV. Analysis

Initially, both parties accept Dr. Novak's October 20, 2016 diagnosis of Ms. DiMasi to include small fiber neuropathy and POTS. Pet'r's Am. Mot. at 7; Resp't's Am. Resp. at 7-8 (citing exhibit 23 at 9 (Dr. Novak's records)). However, the parties disagree on when Ms. DiMasi first developed these conditions. If the petitioner's injury was present before the vaccine was administered, it is not necessary to conduct a complete analysis pursuant to Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380-81 (Fed. Cir. 2012). Thus, a critical question is when Ms. DiMasi first displayed symptoms of small fiber neuropathy and/or POTS.

For the diagnostic criteria of small fiber neuropathy, both Ms. DiMasi and the Secretary rely on the Lacomis article (exhibit 24-M).⁶ Pet'r's Am. Mot. at 7; Resp't's Am. Resp. at 12. Lacomis states that individuals with small fiber neuropathy present with tingling, burning, prickling, shooting pain or aching, and sometimes can experience numbness, tightness, or coldness rather than pain. Exhibit 24-M at 2. For the diagnostic criteria of POTS, both Ms. DiMasi and the Secretary rely on the Grubb article (exhibit 24-H).⁷ Pet'r's Am. Mot. at 8; Resp't's Am. Resp. at 13. Grubb states that individuals with POTS present with tachycardia, palpitations, tremulousness, nausea, sweating, and increased blood pressure. Exhibit 24-H at 2. Grubb notes additional symptoms for POTS, notably

⁶ David Lacomis, Small-Fiber Neuropathy, 26 Muscle Nerve 173-88 (2002).

⁷ Blair P. Grubb et al., The Postural Tachycardia Syndrome: A Concise Guide to Diagnosis and Management, 17(1) J. Cardiovasc. Electrophysiol. 108-12 (2006).

including lightheadedness, near syncope, and syncope, with more than half of patients suffering from migraine headaches. Id. at 1.

Relying on Dr. Leist, the Secretary argues that Ms. DiMasi's pre-vaccination medical history of syncope/near syncope, palpitations, and tachycardia establishes that Ms. DiMasi had small fiber neuropathy and POTS since at least 2008.⁸ Resp't's Am. Resp. at 13; exhibit A at 9; exhibit E at 1. Reviewing these pre-vaccination symptoms, Ms. DiMasi first reported an episode of near syncope on March 19, 2008, another episode of near syncope on November 2, 2009, and a possibly alcohol-induced syncope in May 2012. Exhibit 6 at 52; exhibit 16 at 12; exhibit 15 at 21. On August 11, 2009, Ms. DiMasi complained to Dr. Fischer of headache issues and her problem list included palpitations and migraine headaches. Exhibit 15 at 3. On December 7, 2009, Ms. DiMasi complained to Dr. Rho of intermittent mild dizziness for the last month, a reoccurring problem that had returned. Dr. Rho attributed the dizziness to migraine-associated vertigo. Id. at 6. Ms. DiMasi complained of intermittent tingling behind her knees and upper calves to Dr. Fischer on April 18, 2012. Exhibit 15 at 17. Dr. Fischer noted that Ms. DiMasi experienced the tingling "particularly when she sits for prolonged periods of time." Id. The use of "particularly" indicates that Ms. DiMasi had been experiencing tingling for long enough to recognize patterns of when the sensation would come and go.

Dr. Kinsbourne acknowledges Dr. Leist's citing of pre-vaccination episodes of syncope/near syncope, palpitations, and tachycardia, stating that "[it] is not unusual for the onset of POTS to be preceded by miscellaneous episodes of dysautonomia." Exhibit 25 at 2. Moreover, Dr. Kinsbourne notes that migraines, which Ms. DiMasi had since at least 2008, are a "frequent concomitant of POTS," and that "small fiber neuropathy and POTS are frequent associates." Exhibit 24 at 6. Dr. Kinsbourne categorically stated that "there had been no record of Ms. DiMasi experiencing symptoms of neuropathy before the vaccination." Exhibit 25 at 2. However, Dr. Leist noted that Ms. DiMasi's pre-vaccination medical history included peripheral neuropathy, exhibit A at 1 (citing exhibit [15] at 3, Aug. 11, 2009 appointment), and opined, as detailed above, that Ms. DiMasi had small fiber neuropathy for at least a few years before the vaccination.

In her amended motion for ruling on the record, Ms. DiMasi does not address any of her medical history before 2012. See Pet'r's Am. Mot.

⁸ The medical records in this case only go back to 2008.

The undersigned finds that the evidence supports Ms. DiMasi having symptoms related to her small fiber neuropathy and POTS before the December 4, 2012 influenza vaccination. The presence of problems before a vaccination could serve as a predicate for an alternative cause of action—that the vaccination significantly aggravated the pre-existing problem. However, Ms. DiMasi explicitly stated that she is not pursuing a significant aggravation claim. Pet'r's Am. Mot. at 21. Thus, the undersigned will not address whether Ms. DiMasi's pre-existing symptoms worsened after the vaccination.

V. Conclusion

The evidence supports Ms. DiMasi having symptoms related to her small fiber neuropathy and POTS before the December 4, 2012 influenza vaccination. Thus, because Ms. DiMasi has pre-existing symptoms and declined to allege a significant aggravation claim, she is foreclosed from receiving compensation for her vaccine claim. Ms. DiMasi's petition for compensation is DENIED for insufficient evidence.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master